Avoid Maalox Mix-Ups

Maalox Advanced Regular Strength and Maalox Advanced Maximum Strength (left and center) and Maalox Total Relief (right) contain different active ingredients for the relief of different symptoms. Read the labels carefully. Using the wrong product can cause serious side effects in some people.

Product images courtesy of Novartis

Choosing the wrong liquid Maalox product for your condition can have harmful consequences, warns the Food and Drug Administration (FDA).

Consumers may be confused by the similar packaging and labeling of liquid Maalox and Maalox Total Relief. Both products are available without a prescription (over-the-counter) and feature the Maalox name, but they contain different ingredients for the relief of different symptoms.

Maalox Advanced Regular Strength and ***Advanced Maximum Strength*** contain the active ingredients aluminum hydroxide, magnesium

Maalox Total Relief and Maalox are not interchangeable and shouldn't be used in place of each other.

hydroxide, and simethicone for the relief of acid indigestion, heartburn, sour stomach, upset stomach, and pressure and bloating (gas).

Maalox Total Relief Maximum Strength has only one active ingredient—bismuth subsalicylate—for the relief of diarrhea, upset stomach associated with nausea, heartburn, and gas due to overeating.

"Maalox Total Relief and Maalox are not interchangeable and shouldn't be used in place of each other," says Carol Holquist, R.Ph., director of FDA's Division of Medication Error Prevention and Analysis.

Serious Side Effects

FDA has received five reports of serious medication errors in consumers who used Maalox Total Relief by mistake when they had intended to use one of the Maalox liquid antacid products.

Maalox Total Relief is not appropriate for individuals who want to use an antacid, especially if they have a history of ulcers in the stomach or intestine (gastrointestinal ulcer disease) or a bleeding disorder. The bismuth subsalicylate in Maalox Total Relief is chemically related to aspirin and can cause similar side effects, such as bleeding, in some people.

Due to the potential for serious side effects from product confusion, the maker of Maalox brand products has agreed to

- change the name of Maalox Total Relief to one that will not include the name "Maalox" and revise the graphics and information displayed on the front of the product to help distinguish the active ingredients and uses of this product from the Maalox antacids. The company expects to begin selling the renamed product in September 2010.
- carry out an educational program that includes outreach to health care professionals and consumers to inform them about the different products sold under the Maalox brand, including how to select the appropriate Maalox brand product
- monitor the safety of Maalox brand products and report side effects related to their use

Advice for Consumers

"Whether it's Maalox or another over-the-counter product, reading the product label is an important first step consumers can take to be certain they are using the proper product," says Holquist. FDA also recommends the following:

- Check the active ingredients in the "Drug Facts" label before you buy Maalox products or other over-the-counter products to be sure you select the correct product. If your health care professional recommended you take Maalox antacid, do not get Maalox Total Relief, which contains bismuth subsalicylate.
- Read the "Drug Facts" label and container for important product information, including drug warnings, dosage directions, and expiration date. Do not remove the product label.
- Ask your pharmacist or other health care professional for help if you're unsure of which product is right for you.

FDA encourages health care professionals and consumers to report any side effects, product quality problems, product use errors, or therapeutic failure with the use of medical products to FDA's MedWatch Adverse Event Reporting program either online, by regular mail, by fax, or by phone.

- Online at *www.fda.gov/MedWatch*
- Regular Mail: Use postage-paid, pre-addressed FDA form 3500 available at *www.accessdata.fda.gov/scripts/medwatch/*
- Fax: 1-800-FDA-0178
- Phone: 1-800-332-1088

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